


# Workgroup6



## PTProgramDevelopment forResource -Limited CountriesandRegions

**Dr.RobertMartin**



# WHAT ARE SOME OF THE ORGANIZATIONAL STRUCTURES FOR PT/EQ IN RESOURCE -LIMITED COUNTRIES OR REGIONS? ARE THERE SUCCESSFUL PROGRAMS RUN BY THE GOVERNMENT, ACADEMIC, COMMERCIAL, OR MIXED RESOURCE?

- 👍 Need financial support from government or other source
- Institutions or laboratories specializing in one type of PT sample should produce samples for other laboratories.
- 👍 Regional coordinating body – re-distribution of samples within country or state
  - Provision of SOPs for materials production for in-country laboratories preparing samples/slides for PT purposes
    - Need standard guidelines accessing/available; ISO, NCCLS, CAP, CDC
  - Distribution of multiple sets of samples/slides to district level for further distribution to health centers
    - Re-cycling sample sets from district level to health centers
- 👍 Re-checking of slides, however, issues such as re-blinking, results, and sample size to assure adequate confidence must be considered



# WHAT FACTORS HAVE MADE THESE PROGRAMS SUCCESSFUL?

- 👍 Strong in-country government support
- Measure impact of program, e.g., improvement in performance over time
- 👍 Constant communication, troubleshooting, support to participating labs
- 👍 Start small with laboratories that are likely to succeed
- 👍 Pilot new analytes, in consultation
- Transfer of leadership




# IS THERE AN OPTIMAL MODEL FOR SAMPLE ACQUISITION BY PROGRAMS FOR RESOURCE-LIMITED COUNTRIES OR REGIONS?

- ◆ Regionally produced materials according to CAP specifications and re-distribution within countries
- ◆ Engage CAP in discussions for preparation/distribution of samples to developing countries in which infrastructure is now or will be present
- ◆ Donor support for sustainability is required over a number of years



# DO SUCCESSFUL PROGRAMS PURCHASE AN OUTSIDE PROGRAM OR CREATE THEIR OWN WITH ASSISTANCE, OR SOME MIXED?

- ◆ Create own specimens because of costs
- ◆ Alternative – digital images
- ◆ Develop Mentoring Programs - training for developing quality EQA materials



# WHAT ARE THE BASIC REQUIREMENTS FOR DEVELOPING APT/EQA PROGRAM, IN A RESOURCE-LIMITED COUNTRY OR REGION?


- People  
(Champion, Administrator, Collaborating partner)
- Infrastructure  
(Quality Management System, Advisory Group, Facilities, Information Technology, Policy, Political Will)
- Planning  
(Assessment of scope of testing, Implementation Plan)
- Financial Resources  
(Identification of sustainable sources, vertical programs)



# Centralized vs. Decentralized Model

- The choice of a specific model should be made on the basis of the requirements of each specific program





# WHAT ARE THE ADVANTAGES OR DISADVANTAGES OF A DISTRIBUTED NETWORK OF SAMPLE CREATION FACILITIES?


## Advantages

- More local benefits (increased ownership, EQA customized to local requirements) 1
- Simpler logistics (provided redundancy, shipping, language, more sources of PT materials)

## Disadvantages

- Loss of economy of scale  
(more difficult to manage, replication of resources, availability of experts)
- Loss of comparability  
(more difficult to quality control, harmonization barriers)





# WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF USING A SINGLE CENTRALIZED FACILITY TO PREPARE, DISTRIBUTE, AND ANALYZE DATA?

## Advantages

- Standardization, Traceability, Comparability
- Economy of scale  
(expert needs are easier met, larger database)
- Organization benefits (Management, Accreditation, Training, added core business value)

## Disadvantages

- Remote to local needs and more institution -dependent
- Vulnerability due to lack of back -up/redundancy



## WHAT IF ANY, ETHICAL ISSUES NEED TO BE CONSIDERED BEFORE DEVELOPING AND INTER-PROGRAM MENTORING INITIATIVE?

- Establish qualifications and commitment of the mentor to a sustained long-term relationship.
- Full disclosure by the mentor of conflicts of interest.
- Ethical issues with respect to sample acquisition should be dictated by local policy/regulations [and the mentor's country]. Mentor has a responsibility to educate the host country on ethical issues.




# WHAT IS THE ROLE OF A MENTOR IN ESTABLISHING STANDARDS THAT FACILITATE THE DEVELOPMENT OF AN INTER-PROGRAM MENTORING INITIATIVE?

- Mentor should identify local champion [leader]
- Mentor should then enter into a dialog with host country to define the host's expectations for the relationship.
- Mentor and the host country define the milestones and evaluation steps for the project with the long-term objective being to decrease the direct involvement of the mentor in the project. The long-term mentor/host relationship is maintained.
- WHO should be encouraged to develop guidelines that define the mentor/host relationship.




# WHAT ARE THE QUALITY INDICATORS TO MONITOR THE SUCCESS OR FAILURE OF AN INTER-PROGRAMMENT OR IN-INITIATIVE?

- The mentor/host should develop a strategic plan for the project
- Key elements to be included:
  - Define goals, timelines and identify outcome indicators that can be objectively measured. The plans should reflect the expectations as mutually agreed. The long-term performance goals should be consistent with international standards.
- Indicators of success should be predicated upon the timely achievement of the measurable milestones as defined in the strategic plan. Such milestones might include: enrollment, safety plans, continuing educational programs, measures of analytical variance, independence/self-reliance, availability of PT samples, data handling/processing, etc.



# HOW COULD AN INTER -PROGRAM MENTORING INITIATIVE HELP TOWARDS DEVELOPMENT OF SUSTAINABLE PT/EQA PROGRAMS IN RESOURCE - LIMITED COUNTRIES OR REGIONS?


- ◆ Raising awareness/visibility/advocacy for PT
  - Support using data in order to gain resources, etc.
- ◆ Extension of PT effort into overall lab quality (i.e. improvement leading to cost reduction, etc.)
- ◆ Mentoring – collaboration/partnering (in -country and between countries)
  - Can benefit from cost reduction/sharing
  - Can develop regional PT/EQA Programs
  - Less developed programs learning from more developed and from one another
  - Standardization of laboratory practice
  - Provision of technical and material support (data management, tools, etc.)
  - Direct inter -comparability of data



# WHAT ARE THE FACTORS THAT CONTRIBUTE TO THE SUSTAINABILITY OF A PT/EQA PROGRAM?

- ◆ Ensure trainees implement PT programmes in -country
- ◆ Reference lab development (transfer of expertise to peripheral labs)
- ◆ Standardization of program & laboratory practice
- ◆ Ongoing resources
  - Monitoring of standards (accreditation)
  - Government mandated PT programs.
- ◆ Maintenance of equipment (mentoring needed)





# WHAT ARE SOME OF THE INTERNATIONAL AGENCIES, INSTITUTES, OR PRIVATE SECTOR GROUPS THAT COULD FACILITATE FUNDING FOR DEVELOPING INTER -PROGRAMMENT OR INITIATIVES IN RESOURCE -LIMITED COUNTRIES OR REGIONS?

## Financial support

- ◆ U.S.-based organizations (CDC, NIH, USAID, etc.)
- ◆ International organizations/country organizations (WHO/PAHO, World Bank, DANIDA, European Union, etc.)
- ◆ Foundations (Gates, Ford, etc.)
- ◆ Private ISO Registrars (e.g. British Standards Institute)



# Continued....

## Non-financial support

- ◆ Govt/non-govt PT/EQA providers (CDC, CAP, etc.)
- ◆ Associations (IFCC, CAPAPHL, etc.)
- ◆ Independent Consultants
- ◆ Centers of excellence
- ◆ Regional mentors (link to sustainability)

# Continued....

Marketing of PT to agencies for financial support

- ◆ Access to internet vital (provides agency background, what they are looking for, etc.)
- ◆ Development of PT brochure (providing justification) for private or public sector funding

Factors affecting funding

- ◆ Political situation in country may cause agencies to withdraw
- ◆ Funneling mechanisms in -country (do funds reach correct groups?)



# Summary

- ◆ Longtermfundingsupport
- ◆ Longtermpartnerships
- ◆ Regionalresourcesharing
- ◆ Standardization
- ◆ Countryinfrastructure
- ◆ Overallqualitymanagement



# SUBGROUP LEADERS AND RECORDERS

- ◆ JaneCarter
- ◆ JoseCampione
- ◆ GraceKahenya
- ◆ ValerieWilson
- ◆ EveGadzikwa
- ◆ StacyHoward
- ◆ ThomasHearn
- ◆ RogerTaylor
- ◆ BhavnaLall
- ◆ ErloRoth